Senior Regulatory Affairs Consultant, Galway

Position Summary

Responsible for the management of the company's regulatory affairs activities including but not limited to:

- Management of regulatory submissions to regulatory authorities for the company's products,
- Management of routine regulatory activities including clinical evaluation, safety and vigilance reporting and post market surveillance reporting.
- Maintenance of existing global regulatory approvals.
- Supervision and development of direct regulatory team members to ensure timely and successful achievement of regulatory goals.

Principal Responsibilities

- Maintenance of existing CE mark, IDE and PMA files, including US FDA annual reports, EU Substantial Change Notifications, and Post Market Surveillance Reports.
- Management and supervision of MDR, vigilance and clinical safety reporting activities to US FDA, EU Competent Authorities and the Japan legal agent / PMDA.
- Play an active role in the company's EU MDR compliance program.
- Support the preparation of clinical study reports from IDE, OUS and Post Approval clinical studies.
- Review and approve product labelling changes, promotional literature and marketing materials prepared by the Company and its distributors.
- Provide input to regulatory aspects of design control, change control, non-conforming process.
- Provide a regulatory interface to the company's clinical and commercial operations.
- Develop and advise on regulatory strategies for existing and changing products in collaboration with R&D, Manufacturing and Quality Assurance departments, as appropriate.
- Maintain and establish channels of communication with regulatory agencies, vendors supplying clinical operations support, customers, subcontractors, professional societies, consultants and other external bodies as required.

Educational Requirements

Bachelor's or Master's degree in science, pharmacy, engineering or life-sciences related field

Experience

- Minimum 8 years' experience in regulatory affairs, ideally with Class III cardiovascular medical devices.
- Previous experience in drug/device combination product filings highly preferred.
- Understanding of regulatory strategy and determination of documentation requirements, timelines, budgets and filing options.
- Excellent oral and written communication skills. Negotiation abilities to identify and resolve issues; highly organised.

- Prioritise own workload and the workload of the project team to achieve project deliverables.
- Proficient in all Microsoft Office applications.
- Experience of the following standards/regulations: ISO 13485; ISO 14155; 21 CFR 820; 21 CFR 803; 21 CFR 814; 21 CFR Parts 50, 54, 56, 812; MDD; EU MDR; ICH GCP
- Quality management system experience
- Experience of CAPA, Auditing and Risk Management (including FMECA)

To apply, please send your CV and a covering email to: Jo Graver, HR Manager, quoting vacancy ref V103.